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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/738,938

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Raul G. Barletta

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EXAMINER

RAMIREZ, DELIA M

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

10/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	Application No. 10/738,938	Applicant(s) BARLETTA ET AL.	
	Examiner Delia M. Ramirez	Art Unit 1652	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 01 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: 6,11,24,26 and 27.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 12,25,28.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

***ADVISORY ACTION***

1. Claims 6, 11-12, 24-28 are pending.
2. The request for entering amendments to the specification and claims 12, 25-26, 28, and arguments filed on 10/1/2007 under 37 CFR 1.116 in reply to the Final Action mailed on 7/27/2007 are acknowledged. The proposed amendments to the claims and the specification will not be entered. The amendment to the specification does not provide the markings that show the changes made as required by 37 CFR 1.121. While amendments to the claims seem to overcome the objections, and the 35 USC 112, second paragraph rejection of claim 12, the proposed amendments (1) to claim 28 raises new issues which would require further consideration as discussed below, and (2) do not overcome the previous 35 USC 112, first paragraph, enablement rejections previously applied.
3. Proposed amended claim 28 would be rejected under 35 USC 112, second paragraph, due to the recitation of "a corresponding non-transformed microorganism" for the following reasons. As written, the term indicates that there is more than one corresponding non-transformed microorganism, thus encompassing a genus of corresponding non-transformed microorganisms. Therefore, the claim requires a basis of comparison which is variable (the transformed microorganism compared to any species of the genus recited). It is suggested the term be amended to recite "the corresponding non-transformed microorganism".
4. The specification would be objected to for the following reasons. There is no reference to the biological deposits recited in the claims in the specification. As stated in 37 CFR 1.809(d), for each deposit made, the specification shall contain: (1) the accession number for the deposit; (2) the date of the deposit; (3) a description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) the name and address of the depository. It is suggested the specification be amended to include this information in order to comply with the provisions of 37 CFR 1.809(d).

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5. The specification would be objected to for the following reasons. Table 1 refers to certain numbers under the "Reference and/or source column" for which there is no corresponding reference/source. See, for example, reference 5, 7 and 25 as shown in that table. It is suggested that the actual reference be cited instead of the number which is currently present.

6. With regard to claims 24-25, which still require strain GPM265 and vector pMV262, Applicant argues that vector pMV262 was publicly known and refers to references by Connell et al. and Stover et al. as evidence of public knowledge of this vector. Applicant refers to (1) Connell et al. as describing the origin of replication, kanamycin resistance, and hsp60 promoter, and (2) Oka et al., Shinnick et al., Rauzier et al., and Yanisch-Perron et al. as providing the sequences of the origin of replication, kanamycin resistance gene, and the hsp60 gene present in vector pMV262. Applicant also discloses that the rights for pMV262 belong to the Albert Einstein College of Medicine from where the public now has ready access. Applicant further submits that this vector is contained within pBUN276 which is deposited with ATCC as PTA-8190. With regard to strain GPM265, Applicant asserts that (1) this strain is not the strain deposited as PTA-8190, (2) one could produce this strain from strain MC<sup>2</sup> 155 publicly available from ATCC, and the pBUN276 plasmid deposited with ATCC as PTA-8190. Applicant submits that to publish a related article in Antimicrobial Agents and Therapy, the journal requires distribution to the public of both GPM265 and pMV262.

7. Applicant's arguments have been fully considered. In view of Applicant's submission of pages from the ATCC catalog showing that MC<sup>2</sup> 155 is publicly available (ATCC Number 700084) and Table 1 of the specification indicating that strain GPM265 is produced by transformation of strain MC<sup>2</sup> 155 with plasmid pBUN276, the previous 35 USC 112, first paragraph rejection of claim 24 is hereby withdrawn. The Examiner has considered all the evidence and arguments provided with regard to plasmid pMV262. However, these arguments are not found persuasive. As previously indicated, while pBUN276 is derived from pMV262, the plasmid of claim 25 does not have to be pBUN276 as it may contain other elements

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not found in pBUN276 but found in pMV262. The references cited have been considered but contrary to Applicant's assertions, they do not provide the entire sequence of pMV262. Connell et al. merely mentions that the plasmid contains the origin of replication from pAL5000, the pUC19 origin of replication, the aph gene (kanamycin resistance gene), and the BCG hsp60 promoter in the expression site. Stover et al. refers to plasmid pMV261 and not pMV262. See Figure 1 of Stover et al. Even if it is assumed that plasmid pMV261 in Stover et al. is the same as plasmid pMV262 of Connell et al., it is noted that Stover et al. indicates that pMV261 is 4488 bp long and merely provides a nucleotide sequence having 64 nucleotides, which appears to correspond to the cloning site. Thus, even if the sequences of the origins of replication, adh gene, and hsp60 promoter are added, contrary to Applicant's assertions, the combined teachings of the references cited do not provide one of skill in the art with the entire sequence of vector pMV262. With regard to arguments that this plasmid is available to the public from the Albert Einstein College of Medicine, in the absence of any evidence showing that the public has unrestricted access to this plasmid, the Examiner cannot verify whether this vector is publicly available from the Albert Einstein College of Medicine under the conditions set forth in 37 CFR 1.808. With regard to arguments that Applicant has already agreed to distribute the plasmid as a requirement for publication of a manuscript filed with a peer-reviewed journal (Antimicrobial Agents and Chemotherapy), it is noted that the deposit rules in 37 CFR 1.801-1.809 are the rules which set forth examining procedures and conditions of biological deposits. Thus, rules and regulations from different entities are not applicable to issues regarding biological deposits in a patent application.

8. The rejections and objections previously applied, with the exception of the 35 USC 112, first paragraph, enablement rejection of claim 24, are, therefore, maintained for the reasons of record in view of the non-entry of the proposed amendments.

9. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: 6, 11, 24, 26, 27

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Claims(s) objected to: NONE

Claim(s) rejected: 12, 25, 28

Claim(s) withdrawn from consideration: NONE

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.  
Primary Patent Examiner  
Art Unit 1652

DR  
October 24, 2007